

Protocol Title

A Randomized Controlled Trial of 2% Chlorhexidine Gluconate Skin Preparation Cloths for the Prevention of Post-Operative Surgical Site Infections in Colorectal Patients

Principal Investigator

Steven Klintworth, R.N. CCRP
Research Nurse Specialist IV
1211 21st Avenue South
711 Medical Arts Building
Nashville, TN 37212-1050
615-936-5354

Sub Investigators

Matthew McEvoy, M.D.
Edward Sherwood, M.D., Ph.D.
Timothy Geiger, M.D.
Elizabeth Card, MSN, APN, FNP-BC,
Damon Michaels, BS, CCRP

Confidential

Department of Anesthesiology
Vanderbilt University School of Medicine

Table of Contents:

- 1. Background and Significance**
- 2. Hypothesis**
- 3. Study Objectives**
- 4. Methods**
- 5. Patient Population**
- 6. Enrollment**
- 7. Inclusion/Exclusion Criteria**
- 8. Data Collection**
- 9. Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others:**
- 10. Statistical Plan**
- 11. Privacy/Confidentiality Issues**
- 12. Follow-up and Record Retention**

1. Background and Significance:

Surgical site infection (SSI) following colorectal surgery is a frequent complication and results in higher morbidity, mortality and healthcare costs. SSI following adult colorectal surgery is a frequent complication that has been reported to occur in 5%-30% of cases nationally. Vanderbilt's SSI reported rate of infections in colorectal surgeries is currently 8%. Treatment for SSI can be challenging often requiring revision surgery, long-term antibiotics, and prolonged hospitalization. The accurate identification of risk factors is thus important in the development of strategies to prevent these potentially devastating infections. Vanderbilt performs approximately 1,000 colorectal cases per year.

The New CDC-definitions for surveillance of surgical site infections (1992) take into account 3 classes of surgical site infections (SSI): superficial incisional SSI, deep incisional SSI, and organ/space SSI. The most prevalent host-related risk factors for development of SSI are advanced age, morbid obesity, disease severity, an ASA score > 2, prolonged preoperative hospital stay, and infection at distal sites. Microbial contamination of the surgical site occurs mainly during the surgical intervention.

Although exogenous contamination from the surgical suite may be of concern, especially in clean operations, most surgical site infections are caused by microorganisms of the patient's own skin flora. SSI rates vary according to the type and duration of the surgical procedure. Proper surgical technique is probably the most important factor in the prevention of SSI.

Modification of patient risk factors should be attempted whenever possible through use of adequate protocols for antimicrobial prophylaxis with antibiotics should be followed. Routine surveillance of surgical site infections is beneficial for SSI prevention and early detection. Additional prevention aimed at decreasing number of microorganisms on patient's skin pre-operatively may decrease rates of SSI. Prior studies have reported daily use of 2% chlorhexidine gluconate cloths has decreased rates of nosocomial bloodstream infections in those with central line catheters. Another study reported decreasing SSIs up to 50% when nursing staff instituted utilization of 2% chlorhexidine gluconate cloths pre-op and daily post-op cleansing in-hospital. However, use of chlorhexidine cloths pre-operatively has not been routinely instituted. Many hospitals and service lines do not have a protocol for their use. Therefore study of such a population may prove worthy, as currently VUMC colorectal patients use chlorhexidine cloths preoperative on the abdomen, groin and buttocks the night before surgery and again the morning of surgery.

This study proposes a randomized, controlled trial of colorectal patients of 2% chlorhexidine gluconate skin preparation cloths for the prevention of post op surgical site infections in colorectal patients.

2. Hypothesis:

Use of 2% chlorhexidine gluconate cloths pre-operatively and daily post-operatively (neckline to toes) will decrease surgical site infections (SSI) by 30% (study group) when compared to patients who use chlorhexidine cloths night before surgery and morning of surgery (control group).

3. Study Objectives:

- Randomize consented patients pre-operatively to either the study group (of 2% chlorhexidine gluconate cloths pre-op night before day of surgery and daily post-

op cleansing) or the control group with follow-up through discharge for evaluation of SSI

- Evaluation for SSI development at 30 day (+/-) post-op visit.
- Measure change in skin flora by comparing skin swab cultures of those in the study group versus those in the control group at time of consent (baseline), pre-operative, day 4 post-operative, or day of discharge whichever comes first, and at the 30 day follow up.

4. Methods:

Patients scheduled for colorectal surgery will be evaluated and approached for interest. Consented subjects will be randomized in a 1:1 ratio (approximately 75 subjects per treatment arm) through a block randomization table. Those enrolled into the study arm will receive the 2% chlorhexidine gluconate cloths and instructions for use from research personnel. The subject will wash themselves neck to toe using Chlorhexidine gluconate wipes per study instructions the night before. Study staff will perform the CHG wipe application on the day of surgical procedure. They will then receive post-op daily skin cleansings per protocol by research personnel until post op day 4 or discharge from the hospital, whichever comes first.

Subjects randomized to the control arm will receive Chlorhexidine gluconate wipes and instructions for use per the previous colorectal surgical policy (prior to September 2017).

On the day of surgery all subjects will have an abdominal skin swab culture taken after cleansing with Chlorhexidine gluconate wipes. We will also obtain abdominal skin swab cultures at site of incision post-op day 4, or day of discharge and at the 30 day follow up (+/- 7 days).

Both groups will be evaluated daily by study personnel for the development of SSI until post-op day 4 or hospital discharge whichever one comes first. A high definition picture will be taken each day of the incision line to further document signs of SSI development (pictures will not have any patient identifiable information) Additional evaluation will take place at the 30 day post-op visit. Measured change in skin flora will be performed by comparing skin swab cultures of control group vs study group.

Subjects will be withdrawn from the study if they are transferred to a hospital unit that is not one of the acute care post-operative hospital units (eg: not on 3/4 RW or 9 N/S).

Procedure							
Study Day	Screening	Surgical Procedure	POD 1	POD 2	POD 3	POD 4 or Discharge	30 (+/- 14 days) Follow-up
Written informed consent/HIPAA	X						
Inclusion/Exclusion Criteria	X						
Randomization Number Assigned	X						
Medical History	X						
Urine Pregnancy Test		SOC					
Chlorhexidine gluconate skin preparation (Research Arm)	X ¹	X	X	X	X	X	

Chlorhexidine gluconate skin preparation (control)	X	X					
CULTURE OTHER SOURCE (CDM 60930104 - CPT 87070)	X	X ³				X	X
Height / Weight	X						
Vital Signs	X	X	X	X	X	X	X
Post-surgical assessments		X ²	X ²	X ²	X ²	X ²	X ²
Post-surgical photograph			X	X	X	X	X
Blinded assessment of photographs							X
Assess Adverse events	X	X	X	X	X	X	X
Prior Medication Recording	X						
Concomitant Medication Recording		X	X	X	X	X	X

1-Participants will be given supplies at screening. Application will be done by participant on the evening prior to surgery.

2-Post-surgical assessments include documentation of any complications.

3-Culture taken after chlorhexidine wipes; before surgical scrub and draping

5. Patient Population:

Colorectal surgical patients at Vanderbilt University Medical Center

6. Enrollment:

150 patients will be enrolled.

7. Inclusion/Exclusion Criteria:

Inclusion Criteria

1. Patients \geq 18 years old scheduled for a colorectal surgical procedure ASA \geq 2 OR pre-operatively hospitalized

Exclusion Criteria

1. Unable to consent
2. Known allergy to any of the ingredients contained in SAGE chlorhexidine gluconate cloths
3. Current infection or history of abdominal infections.
4. Patients on chronic steroids or immunosuppressive medications.

8. Data Collection:

Data regarding demographics, health history and status, surgical course and hospitalization will be collected and entered into an electronic database. Patient data will be de-identified once it's entered into the database. Shared data will always be de-identified and accessed through Redcap, a secure web-based system.

9. Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others:

Events determined by the Principal Investigator (PI) to be unanticipated problems involving risks to subjects will be reported by the PI or sub-investigator to the IRB within 10 working days of the Investigator's knowledge of the problem.

10. Statistical Plan:

We are planning a study of independent cases and controls with 1 control(s) per case. Prior data indicate the rate of infection in the control group (those with risk factors, including superficial SSI) is 0.5, then just 150 are needed to detect a 50% or greater reduction, with 80% power. We can also design a statistical analysis plan that uses the grade of SSI instead of binary yes/no to indicate presence of SSI. This should increase the power as well, for instance, if the SAGE cloths reduce the severity of (but does not completely prevent) infection in some patients.

11. Privacy/Confidentiality Issues

All reasonable efforts will be made to keep a patient's protected health information (PHI) private and confidential. There will be limited access to electronic medical records and de-identification of all records. Federal privacy guidelines will be followed when using or sharing any protected health information.

Data will be stored in Redcap, a secure web-based database conforming to the latest Vanderbilt IS security policies. Data from the study will be reported only in the aggregate.

A member of the research team at Vanderbilt University will travel to the other sites to assist with data collection. Under the supervision of each site's PI, Vanderbilt research team members will view research records and collect data as identified above. Medical records will be stored separately from the data and remain on-site. All de-identified data-points will be entered directly into Redcap, a secure web-based database. No identified information will leave the site.

All study staff have completed employee education regarding patient confidentiality and have completed Human Subjects protection education (CITI course) as specified by the Vanderbilt IRB.

Through these interventions, we expect risks to privacy to be minimized.

12. Follow-up and Record Retention

Research Records will be retained by the Department of Anesthesiology for a period of six (6) years after the submission of the final report and close-out procedures on the research project for which the Research Records were prepared.

The retention of the original Research Records shall be the responsibility of the Principal Investigator on behalf of Department of Anesthesiology, but at all times shall remain the property of Department of Anesthesiology, unless otherwise specified by law, regulation or agreement.

References

- Fry, D.E. (2013, December 19). The prevention of surgical site infection in elective colon surgery. *Scientifica (Cairo)*, 2013: 896297. doi: [10.1155/2013/896297](https://doi.org/10.1155/2013/896297).
PMCID: PMC3881664.
- Grade, M., Quintel, M. and Ghadimi, B. M. (2011, June). Standard perioperative management in gastrointestinal surgery. *Langenbeck's Archives of Surgery*, 396(5): 591–606. Doi: [10.1007/s00423-011-0782-y](https://doi.org/10.1007/s00423-011-0782-y). PMCID: PMC3101361
- Kobayashi M, Mohri Y, Inoue Y, Okita Y, Miki C, Kusunoki M. (2008, Jun). [Continuous follow-up of surgical site infections for 30 days after colorectal surgery.](#) *World Journal of Surgery*, 32(6),1142-1146. Doi: 10.1007/s00268-008-9536-6. PubMed PMID: 18338205.
- Konishi T, Watanabe T, Kishimoto J, Nagawa H. (2006). [Elective colon and rectal surgery differ in risk factors for wound infection: results of prospective surveillance.](#) *Annals of Surgery*, 244(5), 758-763. PubMed PMID: 17060769; PubMed Central PMCID: PMC1856583.
- National Collaborating Centre for Women's and Children's Health (UK). Surgical Site Infection: Prevention and Treatment of Surgical Site Infection. London: RCOG Press; 2008 Oct. (NICE Clinical Guidelines, No. 74.) Available from:
<http://www.ncbi.nlm.nih.gov/books/NBK53731/>
- Smith RL, Bohl JK, McElearney ST, Friel CM, Barclay MM, Sawyer RG, Foley EF. (2004). [Wound infection after elective colorectal resection.](#) *Annals of Surgery*, 239(5), 599-605; discussion 605-7. PubMed PMID: 15082963; PubMed Central PMCID: PMC1356267

Stulberg JJ, Delaney CP, Neuhauser DV, Aron DC, Fu P, Koroukian SM. (2010). Adherence to surgical care improvement project measures and the association with postoperative infections. *JAMA*, 303(24), 2479-2485. doi:10.1001/jama.2010.841.

Watanabe M, Suzuki H, Nomura S, Maejima K, Chihara N, Komine O, Mizutani S, Yoshino M, Uchida E. (2014). [Risk factors for surgical site infection in emergency colorectal surgery: a retrospective analysis.](#) *Surgical Infections*. 15(3), 256-261. Doi: 10.1089/sur.2012.154. PubMed PMID: 24810804.

CONFIDENTIAL